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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/718,996	11/21/2003	Ning Wei	KCX-742 (19795)	KCX-742 (19795) 9086	
22827 75	590 09/19/2006		EXAM	EXAMINER	
DORITY & MANNING, P.A. POST OFFICE BOX 1449			DIRAMIO, JACQUELINE A		
GREENVILLE, SC 29602-1449			ART UNIT	PAPER NUMBER	
	•		1641		

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)			
	10/718,996	WEI, NING			
Office Action Summary	Examiner	Art Unit			
	Jacqueline DiRamio	1641			
The MAILING DATE of this communication app		<u> </u>			
Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period was Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tiruit apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. ED (35 U.S.C. § 133).			
Status					
1) Responsive to communication(s) filed on 13 Ju	ine 2005.				
2a) ☐ This action is FINAL . 2b) ☑ This					
3) Since this application is in condition for allowan	☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims					
4) Claim(s) 1-36 is/are pending in the application. 4a) Of the above claim(s) is/are withdraw 5) Claim(s) is/are allowed. 6) Claim(s) is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) 1-36 are subject to restriction and/or e	vn from consideration.				
Application Papers					
9) The specification is objected to by the Examiner 10) The drawing(s) filed on is/are: a) acceedable and applicant may not request that any objection to the	epted or b) objected to by the				
Replacement drawing sheet(s) including the correcti 11) The oath or declaration is objected to by the Ex-	on is required if the drawing(s) is ob	jected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 					
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Do 5) Notice of Informal F 6) Other:				

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 1 14, drawn to a method for detecting an analyte, classified in class 436, subclass 501.
- II. Claims 15 22, drawn to a method for detecting an antigen, classified in class 435, subclass 7.1.
- III. Claims 23 36, drawn to a flow-through assay device, classified in class435, subclass 287.2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a different mode of operation, function and effect.

Group I is a method for detecting an analyte requiring detecting an <u>analyte</u> residing in a test sample, wherein the analyte binds to the capture reagent at said scavenging zone, which is not required by the method of Group II.

Group II requires a method for detecting an antigen requiring detecting an antigen residing in a test sample, wherein the antigen binds to an antibody included with the capture reagent in the scavenging zone, which is not required by the method of Group I. Group II further requires the antigen to include C-reactive protein, which is also not required by the method of Group I.

Inventions (I or II) and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process, such as separation or filtration.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, and because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

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distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jackie DiRamio Patent Examiner Art Unit 1641

> LONG V. LE 69/04/06 SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600